

REMARKS

Applicants have the following comments in support of this amendment.

I. Claim Amendments - Reference To The Disclosure

In order to clarify the claimed sanitizing compositions of the present application, Applicants are amending independent Claims 1 and 9. In particular, Claim 1 has been amended to incorporate the material of formerly dependent Claims 2 and 3, which have been canceled without prejudice or disclaimer. Similarly, Claim 9 has been amended to incorporate the material of formerly dependent Claim 11, which has been canceled without prejudice or disclaimer. Independent Claims 1 and 9 have also been amended to incorporated details of presently preferred ranges of concentration for non-volatile antimicrobial agent, the upper limit of 0.04% being based on Applicants' disclosure of unanticipated synergistic activity of such compositions, as for example, described in paragraphs [0041], [0044], [0045], [0065] and [0070], along with Applicants' assay data shown in Tables 1 and 4.

Based on Applicants' election of triclosan as the preferred non-volatile antimicrobial agent, Claims 4 and 14 have been canceled without prejudice or disclaimer.

Therefore, the amendments to the claims have not added any new matter and are clearly supported by the original application as filed. Hence, it is respectfully requested that this amendment be entered and considered at this time.

Applicants will now address each of the Examiner's objections and rejections in the order in which they appear in the Office Action

I. Specification

In the Office Action, the Examiner objects to the Abstract as containing legal phraseology, and in particular, objects to the word “said.” Accordingly, Applicants are amending the Abstract to change “said” to “the.” It is respectfully submitted that this overcomes the Examiner’s objection, and it is requested that the objection be withdrawn.

II. Claim Rejections - 35 U.S.C. §102

The Examiner rejects claims 1-3, 5 and 7 under 35 U.S.C. §102(b) as being anticipated by Scholz (U.S. Patent 5,908,619). This rejection is respectfully traversed.

In particular, the claims of the present application are directed to binary sanitizer preparations comprised of an alcohol and a low-concentration, non-volatile antimicrobial agent (i.e., triclosan) that exhibit unanticipated bactericidal synergy. As explained *supra*, in order to clarify the claimed invention, Applicants have amended independent Claim 1 to recite that the non-volatile antimicrobial agent in the sanitizing composition of the present application is present in a concentration between greater than 0% and equal to or less than 0.04% w/w. As explained below, Applicants have discovered that such a low-concentration has unexpected results and benefits.

In contrast, Scholz does not disclose or suggest a non-volatile antimicrobial agent in the claimed concentration. Instead, the disclosure in Scholz is directed to much higher concentrations and is limited to compositions that exhibit no unanticipated bactericidal synergy and which are consistent with well known prior art.

Specifically, the prior art, including that of Scholz as well as Jones et al. and Johnson et al. (the latter two references having been cited in paragraph [0064] of the specification of the present

application), show that certain compositions containing alcohol and an additional antimicrobial agent at relatively high concentrations (i.e., 0.25% or higher triclosan in the case of Jones and 0.75% or higher triclosan in the case of Johnson) have enhanced activity over compositions containing alcohol alone. In the case of Scholz, no concentration is disclosed for triclosan (see col. 17, lines 31-67). However, Scholz states that the most preferred additional antimicrobial is chlorhexidine, and that the most preferred antimicrobial is chlorhexidine digluconate (CHG) (see col. 17, lines 50-55). Scholz then states that CHG is “preferably present at a concentration of 0.05-5.0%, more preferably about 0.1-3%, even more preferably about 0.25-2%, and most preferably about 0.5-1%.” (col. 17, lines 55-59). Each of these amounts are consistent with the known antimicrobial properties of such agents. Further, each of these amounts is outside the claimed range.

In contrast to this disclosure, Applicants have made an unexpected discovery. Applicants’ data in Tables 1 and 4 of the present application show that the minimum bactericidal concentration (MBC) for a binary preparation consisting of alcohol and triclosan are equivalent to far less than 0.4 mg/L against both *S. aureus* and *E. coli* (i.e., 0.04% triclosan in 60-70% alcohol) (see paragraphs [0065] and [0066] in the specification). These results are unexpected in light of the prior art, as evidenced by the data in Applicants’ Tables 1 and 4. Tables 1 and 4 demonstrate a synergistic effect between the alcohol component and the antimicrobial component for the claimed compositions and no such effect for the prior compositions. Specifically, Table 1 shows that Applicants’ binary preparations of the claimed invention are approximately 100-fold more bactericidal against *S. aureus* than would be predicted based on an additive effect for the individual antimicrobial agents. Similarly, the data in Table 4 show a greater than 100-fold increase in bactericidal activity *E. coli* of the claimed invention relative to that predicted based on such an additive effect. Thus, the binary

sanitizer preparations comprised of alcohol and a low-concentration, non-volatile antimicrobial agent (i.e., triclosan, at a concentration of equal to or less than 0.04%) of the present invention exhibit unexpected bactericidal synergy.

Thus, Schotz not only fails to teach the specific composition claimed by Applicants but fails to predict or achieve the bactericidal synergy discovered by Applicants. This synergy allows Applicants' claimed compositions to work more effectively than prior compounds, while using a substantially lower level of antimicrobial component relative to that described in the prior art, and to also achieve other advantages of reduced exposure of users to the antimicrobial component (which can be irritating to the skin) and reduced cost of such compositions (since antimicrobial components are generally relatively costly components relative to the alcohol base). These other advantages are described for example in paragraph [0066] of the specification of the present application.

Therefore, independent Claims 1 and 9 and those claims dependent thereon are not disclosed or suggested by Scholz, and Claims 1 and 9 and those claims dependent thereon are patentably distinct over Scholz. Accordingly, it is respectfully requested that this rejection be withdrawn.

III. Claim Rejections - 35 U.S.C. §103

The Examiner also rejects claims 6, 8-11 and 13-16 under 35 U.S.C. §103(a) as being unpatentable over Scholz. This rejection is also respectfully traversed.

As described *supra* with regard to the section 102 rejections, Scholz fails to teach a sanitizing composition having a concentration of antimicrobial component of 0.04% or less, as specified in amended independent Claims 1 and 9. Instead, the compositions of Scholz are predicated on use of antimicrobial components at a concentration of 0.05% or greater ("preferably" much higher), as

noted by the Examiner on p. 5 of the Office Action.

Therefore, the rejected claims are not disclosed or suggested by Scholz but are patentable thereover. Accordingly, it is respectfully requested that this rejection be withdrawn.

Conclusion

For at least the above-stated reasons, it is respectfully submitted that the claims of the present application are in an allowable condition and are patentable over the cited references. Accordingly, it is requested that the application now be allowed.

If any further fee should be due for this amendment and/or the extension of time, please charge our deposit account 50/1039.

Favorable reconsideration is earnestly solicited.

Respectfully submitted,

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